



Getting Through Clearance

The most frequently asked question in the clearance process is **"What is the status of my clearance request?"** Clearance requests (i.e., articles, abstracts, presentations) are submitted through the EPO supervisors, who review, clear, and then submit them to the Division ADS. After the Division ADS approves the requests, they are logged into the EPO clearance database by the Division clearance contacts, who submit the hard copies to the Office of Scientific and Health Communications (OSHC). When the hard copies arrive at OSHC, their status is updated in the database. OSHC submits them to editors if necessary before they are sent to the EPO ADS for final approval. Either the division or EPO ADS might determine that a request requires cross-clearance, which OSHC coordinates via contacts in other CIOs. Your paper may be anywhere in this process. Information on how to check the status of a paper in clearance is found at the end of this article.

An analysis of the EPO clearance database showed that majority of the clearance requests submitted to the EPO Publications Clearance Process were cleared within 2 weeks, most within 1 week from the time the requests were received in OSHC. This does not, however, take into consideration the time it might take to clear within the division or branch.

When cross-clearance is required, a request may take longer to clear – you should allow an additional 4 weeks. Occasionally, there are problems in the process such as incomplete forms or misplaced requests that could delay approval and notification. **It is ultimately the authors' responsibility to make sure that clearance requests successfully make it through the clearance process before submitting to a journal or conference.**

Continued on page 4: Clearance

INSIDE THIS ISSUE

- 1 Getting Through Clearance
Ethical Dilemmas in Public Health
- 2 Authorship
- 3 Web Clearance
Closing Out Your Study
- 4 Contracts, Grants, Cooperative Agreements
and PGO Requirements



Ethical Dilemmas in Public Health

Scenario 1 – An EPO fellow assigned to a state health department was involved in a program evaluation to assess the success in reaching the target population. The assignee believed that some interesting findings could be useful to other programs and later decided to write an article to report these findings.

Issue 1 – The assignee obtained approval from the state and submitted the article to a journal without first obtaining CDC clearance. The article includes the assignee's name and CDC affiliation. Is it okay to submit the article to a journal without obtaining CDC clearance?

No, CDC clearance is needed.

Issue 2 – The assignee wrote an article for the state's newsletter as part of her assignment, which does not mention her name or CDC affiliation. Does she need to obtain CDC clearance for the article?

No.

Issue 3 – The assignee obtained clearance from the state and submitted the article for CDC clearance. While waiting for CDC to clear the article, the assignee decided to submit it to a journal since she has already received clearance from the state. Is it appropriate to submit it to the journal before receiving an approval from CDC?

**No.*

Scenario 2: Deadline approaching fast! An EPO author submitted an abstract for clearance late. Feeling that the topic was not controversial and expecting that it would be cleared, the author decided to submit the abstract to a conference without first obtaining clearance. Is this an appropriate option?

**No. The author needs to plan ahead to allow time for proper clearance. Abstracts are usually published as part of meeting proceedings and therefore need CDC clearance before submission.*

*Note that failing to follow proper procedures such as bypassing CDC clearance process is considered scientific misconduct and the supervisor(s) should take appropriate disciplinary actions to resolve the situation.

Continued on page 4: Ethics



Authorship

Authorship issues should be addressed early on at the beginning of a project and documented in writing to prevent potential future problems. The general guidelines for determining authorship and for resolving conflicts can be found in the *Authorship of CDC or ATSDR Publications* (<http://www.cdc.gov/od/foia/policies/author.htm>). This document does not, however, contain guidelines for resolving unusual authorship issues, such as group authorship. Some examples and recommendations for dealing with unusual authorship issues are presented below, as well as the CDC general guidelines for resolving conflicts.

Group/Committee Authorship

When a group or committee conducts a project where no one person can claim greater responsibility than others, group authorship may be appropriate. Group authorship is a way of giving everyone working on a project equal credit. All members of the group must meet the criteria for authorship. The designation can be represented by a collective title and a footnote that lists the names of the individual authors and their institutions. Refer to Uniform Requirements for Manuscripts Submitted to Medical Journals (www.acponline.org/journals/annals) for further information regarding group authorship.

When one or more authors have the responsibility for drafting the paper, the *Journal of American Medical Association (JAMA)*- <http://jama.ama-assn.org/info/auinst.html> recommends using the byline "Jane Doe and the Collaborative Study Group." When one or more persons take responsibility for the group and the other group members are not considered authors, JAMA recommends the byline "Jane Doe for the Collaborative Study Group."

In some instances, authors from collaborating sites are listed by their names and affiliations according to the order determined by a coordinating committee. One or more persons may have lead responsibility for drafting the paper. This person is usually listed first. The paper must be reviewed and approved by all committee members.

Authors Whose Names are Omitted

Authors are sometimes not given proper credit or contributors may feel that they deserve authorship, but

were not credited properly when the paper was published. Sometimes, a person may decline authorship role at the outset of an investigation, but later wishes to participate, but only after the paper is successfully through clearance. Many problems contribute to authors being left out, e.g., miscommunication, misunderstanding, or perhaps something more serious. **The general rule in dealing with these issues is that authors should try to work out these conflicts among themselves before asking for resolution on a higher level.**

The most important tool for resolving conflicts is perhaps the initial documentation of agreements developed at the beginning of the project. This agreement should define the criteria for authorship and outline each person's role, order of authorship, and other types of credit, e.g., acknowledgements. Authors who wish to pursue corrections to omissions should contact the original journal. Still, other situations that cannot be resolved among co-authors might need outside mediation.



General Guidelines for Resolving Conflicts

Clearance Procedures for Scientific and Technical Documents-www.cdc.gov/od/foia/policies/clearance.htm

Conflicts can surface despite careful planning. Most conflicts can usually be resolved between co-authors. The guiding principle in conflict resolution is that the conflict should be resolved at the lowest possible level. The following are CDC guidelines for resolving conflicts:

- *For conflicts between disputants within and among CIOs*

The disputants should try to resolve the conflict among themselves. If the conflict persists, they should proceed to resolution through their respective supervisory channels. If a satisfactory solution is not achieved, the disputants may meet with their respective Assistant or Associate Directors for Science (or other person designated by the CIO Director) to arrive at resolution. If all else fails, the disputant(s) and/or supervisors and/or Assistant or Associate Directors for Science (or other person designated by the CIO Director) may go to the Associate Director for Science, CDC, for final resolution.

- *For Disputes Among CDC and External Collaborators*

The disputants should try to resolve the conflict among themselves. If a satisfactory solution is not achieved, then the disputants may ask their supervisors and/or Assistant or Associate Directors for Science or equivalent and/or the Associate Director for Science, CDC, to mediate.



Web Clearance

Materials to be posted on the Internet must first be cleared through the same channels as materials for publication in print media. Thus, clearance forms for Internet material, including the IRMO development server URL where the edited, scientifically cleared website version resides, should be routed to EPO's Webmaster after review by the Office of Scientific and Health Communications (OSHC) and EPO's Associate Director for Science (ADS). In other words, the version sent for Webmaster clearance should reflect editing and scientific clearance, and it will be a version deemed ready for Internet posting. After undergoing review by the Webmaster, the material will be returned to the author to incorporate suggested changes. The author should then submit the final cleared version to the Webmaster for Internet publishing. Time-sensitive items (e.g., those related to emergency situations or outbreaks) will be given priority and cleared as quickly as possible.

- Materials that can be posted on the Internet without clearance

Materials cleared for publication elsewhere and items already published in hard-copy format need not be cleared again before they are posted on the Internet unless the division director determines that the material contains substantial changes. However, all material must still be routed through OSHC for information and approval by the ADS. In some cases, a journal may have copyrighted the format of an article by a government employee. The author should negotiate with the journal beforehand to allow publication of the article in the same format on the Internet.

- Pdf files and other documents, including published manuscripts, to be attached to a website for downloading are considered regular documents (not Internet Materials) and are cleared in the usual fashion.

Disclaimers

When programs wish to post material by non-CDC persons to their website, a disclaimer should provide a clear indication that the material is from an outside source and not the work of CDC or an official endorsement by CDC. Weblinks to outside sources should also include a disclaimer.

- **Example disclaimer for documents**

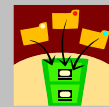
This document is provided solely as a service to our users. It has not been subjected to the Centers for Disease Control and Prevention (CDC) clearance process. CDC does not endorse this document and is

not responsible for its contents. (Include additional information about the specific document).

- **Example disclaimer for Internet links (from CDC Internet Website)**

Links to non-federal organizations found at this site are provided solely as a service to our users. These links do not constitute an endorsement of these organizations or their programs by CDC or the Federal Government, and none should be inferred. CDC is not responsible for the content of the individual organization Internet pages found at these links.

For more information, contact Demetri Vacalis, EPO Webmaster (dvacalis@cdc.gov or 404-639-3183).



Closing Out Your Study

Attention EPO staff! If you will be leaving EPO or CDC in the near future, you must wrap things up before moving on to your next destination. This includes closing out any current project you might have, including research study or transferring research oversight to your destination CIO.

- **Termination of CDC Oversight**

You must submit a formal request to terminate CDC oversight of your research protocol before your CDC employment ends. If a termination request is not received, CDC will terminate oversight of the study upon notification of your departure. You should **avoid involuntary termination** of your research study, because it might look unfavorable on your record, and by regulation is reportable to the Office of Human Research Protection (OHRP/HHS). However, a state or local IRB should still have oversight of the study if you continue working for the state or another local investigator takes over the study.

Submit a formal termination request using CDC IRB form **1253 "Request for Termination."** Be sure to include a copy of your publication or the final draft if not yet published.

- **Transfer of Oversight to Another CIO**

Inform the EPO ADS Office of your new CIO. The EPO ADS will request transfer of oversight to your new CIO.

- **Publication Clearance**

Any publication relating to a project conducted while you were a CDC employee must be cleared through CDC even if you are no longer an employee. Submit your clearance request through your former CDC supervisor as you would while you were a CDC employee. If you transfer to another CIO, any publication of work performed while at EPO should be submitted to EPO for primary clearance. EPO OSHC will facilitate cross clearance with your new CIO.



Helpful Tips for Expediting Clearance

Below are some helpful tips for expediting the clearance process. As a general rule, always plan ahead with enough time to get your requests through, building in additional time for any possible revision or cross-clearance that may be needed.

CDC Clearance Form 0.576

- Fill out the CDC Clearance Form 0.576 as completely as possible.
- Obtain initials of all co-authors or provide e-mail confirmations from all co-authors indicating their approval of the submission.
- Include the date you need your request cleared under the “Date Required” field, particularly if you are requesting RUSH clearance.
- Include the EPO **Human Subjects Review Tracking number** (HSR#) when applicable. The HSR# is internal to EPO (not IRB) and is assigned to a project when human participants are involved or expected to be involved in a project, whether the project is research.

RUSH Clearance

- Include the reason(s) for requesting RUSH clearance, e.g., if an author came across an unexpected deadline, if there is a family emergency, or if the author is taking part in an emergency investigation.

Other Information

- Include the **scientific ethics number** for CDC author when the project involves human subjects.
- Include any additional information that will expedite the review process, e.g., deadline for meeting submission or special issue of journal.

Checking Clearance Status

Clearance status can be checked by opening the **EPO Clearance Database** (read-only) using **Access 2000**. The database is currently located at

- **Clifton Road** - O:/Link/Publication Clearance System/EPO Clearance Database
- **Williams Building** - I:/Publication Clearance System/EPO Clearance Database.

Note that the database might not be up to date. You can also find the status of a clearance request by contacting 1) your division clearance contact or 2) **Barb Stallworth** at (404) 639-3572 if you are unable to confirm the status using the database or have problems accessing the database.

Scenario 3 – A CDC scientist co-authored an article with outside collaborators.

Issue 1 - A non-CDC co-author submitted an abstract to a conference. Does the abstract need CDC clearance?

Yes. If CDC co-authors are listed on the abstract, it must be reviewed and cleared at CDC before submission to the conference. If CDC has comments, they should be provided to the external co-author for revision.

Issue 2 – What if the non-CDC co-author already submitted the abstract without informing the CDC co-author?

The abstract still must be reviewed and approved at CDC. If it is not cleared, the abstract should be withdrawn. If the abstract will not be published, or can be modified after the fact, after discussion with the Division ADS and EPO ADS, it might be possible to submit a revised abstract for CDC clearance. Once that version is cleared, changes must be made to the submitted abstract.

Notes - In the previous issue, one of the scenarios raised the concern of supervisors purposely trying to pass research studies off as non-research. Aside from the ethical violation involved, this is also considered scientific misconduct. Scientific misconduct includes failure to follow CDC procedures for obtaining proper clearances or noncompliance with CDC scientific policies. When CDC scientists fail to follow proper procedures, appropriate disciplinary actions should be taken.

Contracts, Grants, Cooperative Agreements and PGO Requirements

Reminder! All contracts, grants, and cooperative agreements funded by CDC must comply with the *Common Rule*, which governs human subjects research. Investigators are required to submit PGO form 0.1267 (**Certification of Fund Availability**) when the final version of the program announcement is submitted, even if a project is not research. The form must be reviewed and signed by the EPO Admin office and the EPO ADS. Prior completion of the EPO human subjects review process will facilitate rapid turnaround of these forms. For more information consult the **EPO Overview of Scientific Procedures**.